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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,453	10/07/2003	Randal A. Stevens	34597.1	4505

32300 7590 06/30/2006

BRIGGS AND MORGAN P.A.
2200 IDS CENTER
80 SOUTH 8TH ST
MINNEAPOLIS, MN 55402

EXAMINER

PADGETT, MARIANNE L

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/680,453

Applicant(s)

STEVENS ET AL.

Examiner

Marianne L. Padgett

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/7/2006 & 4/17/2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-12 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,2 and 4-12 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/17/06.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Art Unit: 1762

1. Applicants amendments of 4/7/2006 have removed some of the 112, second paragraph rejections, i.e. all those except those directed towards the relative terms "high" & "thin". The amendments to the specification clarify the issues objected to on page 4, and the addition of "include, but not limited to" on line 4 thereof will not be considered new matter, since the suggestion of suitable resins did not state that these were the only suitable ones.

2. Claims 1-2 & 4-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of relative terms that lack clear beats and downs in the claim itself, or in a clear definition in the description or in a cited piece of relevant prior art, is vague and indefinite in all the independent claims see "high" in "high gloss exterior finish" and "thin" in "thin uncured layer". It is noted that page 1, lines 3-7 and the top page 4, give some examples of layer thicknesses, however they are not provided as a definition for "thin" layer, nor is it clear whether they are referring to cured or uncured layers' thickness, but the former seems the more likely context. Applicants generally argue that one of ordinary skill would understand these terms in light of the specification, but provided no specifics, no citations, and no reasoning for why one would understand the scope of these terms from the specification, hence their arguments are not convincing, nor have they put forth any statement that would help would understand there intended scopes.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1762

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-two & 4-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanna (6,660,208 B2), in view of Farnworth et al (6,482,576 B1) as set forth in section 4 of the action mailed 12/8/2005.

Applicants have added the limitation to the independent claim 1, which is equivalent to step (a) of independent claims 6, however this limitation was already covered, in that it was noted was recognized as affecting the final size of the object. To paraphrase, in any process that requires the article being made to have a precise size in the end product, i.e. with the tolerances for the size produced are extremely small, any competent technician, let alone designer, would have been expected to figure in the thickness of a coating being applied over the exterior of the item, when calculating the size of the substrate to be coated. It would have been a matter of basic complements to do so with the claimed "your shell", as it is conventional in the art to make this individualized to the person, i.e. the tolerances for what will fit in not fit our small. Claiming a limitation that would be done as a matter of course by any competent practitioner, cannot be considered to provide a patentable limitation to a process.

To reiterate, Hanna teaches making hearing aid shells via stereolithographic techniques,

Art Unit: 1762

where in order to produce biocompatible products, it is necessary to detoxify by extracting cytotoxins remaining from the stereolithographic polymerization procedures, which may involve UV curing. Several different means of doing so are taught, which are inclusive of extracting with alcohols, such as isopropyl alcohol alone, or with use of such alcohols in ultrasonic bath, with teachings on sufficient times for these procedures to extract unpolymerized residues from the stereolithographically constructed hearing aid shells, which affects required detoxification. Thereafter, post UV curing finishes the cure of the produced shell, and it is further taught that it is common practice to further coat hearing aid shells, such as with UV curable lacquer. In Hanna, see the abstract; figures 2-3 & seven; [0001]; [0005]; [0009-10]; [0012]; [0014-15]; [0022-23]; [0030-33]; especially [0039]; and [0042-49].

While Hanna uses an analogous series of steps to applicants' procedure of UV polymerization and extraction/removing for constructing the hearing aid shell, they differ by not giving any similar details for their generically disclosed UV curable coating of that shell. However, Farnworth et al. teach a procedure for coating stereolithographic structures, where they teach their process is applicable to any structure made by stereolithography, which is advantageous for smoothing the surface to get rid of crevices at the layer interfaces on the surface, which are undesirable as they may be unsightly and they may collect dust, dirt and moisture. When Farnworth et al. lift the structure in its final form from the stereolithographic polymer bath, instead of washing any unpolymerized resin from the crevices, they merely drain the excess polymer from the structure so as to leave a coating that fills the crevices, reading on applicants' "thin uncured layer", then they cure by either UV laser or broad beam or flood type UV radiation, after which typical final curing procedures, including washing with alcohol and

Art Unit: 1762

UV post curing may be performed. In Farnworth et al., see the abstract; figures 1 & 6-10; col. 1, line 7-18; col. 2, lines 13-25 & 61-67; col. 3, line 41-col. 4, line 23; col. 5, line 52-col. 6, line 17; col. 8, line 49-col. 9, line 5+; col. 11, line 35-col. 14, line 68, especially col. 12, lines 1-40 & 58-67, col. 13, lines 5-35 & 48-col. 14, lines 13 & 39-57.

It would have been obvious to one of ordinary skill in the art to use the surface smoothing coating procedure of Farnworth et al. to produce the stereolithographic hearing aid shells of Hanna, in order to achieve the advantageously smooth surface as taught in Farnworth et al., as it provides a specific procedure for creating the suggested UV cured coating, and further provides the advantageous elimination of crevices that can collect dirt, as well as being economical in its use of photo polymeric resin, which is not wasted by washing away, and its consideration of how this coating procedure enhances wall uniformity, affecting the size of final object. It would have been further clear to one of ordinary skill in the art, that one would use the detoxification procedures (i.e. use of alcohol in ultrasonic bath or to chemically extract undesirable unpolymerized residues after the initial UV cure) of Hanna on the so produced coating of the stereolithographically produced hearing aid shell, in order to have a biocompatible product after final cure.

5. Other art of interest includes Sauerhoefer (5482659) who teaches a stereolithographic process including post-processing steps of submerging in alcohol with ultrasonic agitation, drying & UV post-treatment curing. Also Hanna (US 666-0208 B2) is equivalent to the EPA reference to the same inventor discussed above. Johnson et al. (2005/0175925 A1) teach a specific composition and structure of photocurable material for

Art Unit: 1762

making three the objects with generally smooth surfaces when cured, which may be used for making housings for hearing aids (abstract & [0011], etc.).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne L. Padgett whose telephone number is (571) 272-1425.

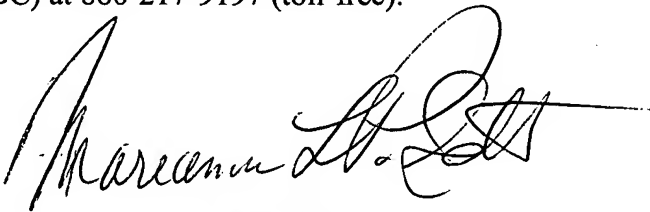
The examiner can normally be reached on M-F from about 8:30 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks, can be reached at (571) 272-1423. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MLP/dictation software

6/25/2006



MARIANNE PADGETT
PRIMARY EXAMINER